

REMARKS

Claims 1-5, 7 and 9-11 are pending in the present Application. Claims 1, 3 and 4 have been amended, leaving claims 1-5, 7 and 9-11 for consideration upon entry of the present Amendment. Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

Examiner Interview

Applicants thank the Examiner and Supervisory Examiner Bridget Bunner for the courtesy of a telephonic interview with Applicant's representative (Lynn Stewart) on August 10, 2011. Possible claim amendments were discussed in view of the English translation of Korean priority document KR 10-2003-0037060, as were possible methods to correct errors identified in the English translation.

Claim Amendments

Claim 1 has been amended to remove the term "*sugar alcohol*" and to insert the term "*mannitol*". Claims 3 and 4 are amended to remove phrases including the previously claimed sugar alcohol in order to address any issues related to antecedent basis.

Support for the amendment to claim 1 is found in the specification as originally filed at least on page 9, lines 11-14. Applicants contend that support for the amendment to claim 1 is also found in the Korean priority document KR 10-2003-0037060, filed June 10, 2003 (hereinafter "the Korean priority application").

On June 25, 2009, Applicants submitted a certified English translation of the Korean priority application (hereinafter "the original English translation"), thereby perfecting Applicant's priority claim to the date of June 10, 2003. In the last paragraph on page 10 (lines 19-25), beginning in line 24 and ending in line 25, the original English translation states "*The amount of the sugar alcohol is preferably 0.1 to 1.0% (w/v)*". In preparing a response to the present Office Action, it was noted that there is an error present in the above-referenced sentence of the original English translation. Specifically, the term "sugar alcohol" in the original English translation, is actually "mannitol" in the Korean priority application.

Submitted herewith are two separate, certified English translations of the 23 paragraph on page 13 of the original Korean priority application (hereinafter "new English translation" or "new English translations"). The 23 paragraph on page 13 of the Korean priority application

corresponds to the last paragraph on page 10, lines 19-25, of the original English translation. Each new English translation was independently prepared by one of two individuals, Soo-Kyung Cho and Hyo-Jin Kang, who are conversant in both English and Korean languages. As shown in the new English translations, the last sentence in the 23 paragraph on page 13 of the Korean priority application states "*The amount of the mannitol is preferably 0.1 to 1.0% (w/v)*".

Also submitted herewith is a declaration under 37 C.F.R. 1.132 signed by translator Soo-Kyung Cho and a declaration under 37 C.F.R. 1.132 signed by translator Hyo-Jin Kang. The declarations each establish that an error exists in the original English translation, that the error lies in the sentence "*The amount of the sugar alcohol is preferably 0.1 to 1.0% (w/v)*", and that the corresponding sentence in the Korean application 10-2003-0037060 actually states "*The amount of the mannitol is preferably 0.1 to 1.0% (w/v)*". Each declaration further states that the attached, corresponding new English translation is a true and correct translation into the English language.

Therefore, for all of the above reasons, Applicants contend that support for the amendment to claim 1 is found in the Korean priority application as evidenced by the new English translation(s) submitted herewith.

Applicants are not conceding that the amended claims would not have been patentable without the present amendments. The present claim amendments are intended only to facilitate expeditious allowance of valuable subject matter. Applicants respectfully reserve the right to present and prosecute the original versions of the amended claims in or more continuing applications.

Claim Rejections Under 35 U.S.C. § 102(e)

Claims 1-5, 7, 9-11 stand rejected under 35 U.S.C. § 102(e), as allegedly anticipated by Vukmirovic (WO 2004/006958 A1). Applicants respectfully traverse this rejection.

To anticipate a claim, a reference must disclose each and every element of the claim. *Lewmar Marine v. Varient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987).

Vukmirovic is prior art only under 35 U.S.C. § 102(e).

In making the rejection, the Examiner stated that Applicant cannot rely upon the foreign priority because the invention as claimed in the instant application is not described in foreign priority document Korean application KR 10-2003-0037060. (OA 05/30/11, page 5)

In order to facilitate prosecution and the allowance of the claims, Applicants have amended the claims to replace the term “sugar alcohol” with “mannitol”. Amended Claim 1 is now directed to an aqueous formulation of human erythropoietin, comprising the human erythropoietin, a non-ionic surfactant, 0.001 to 0.1% (w/v) of a polyhydric alcohol, a neutral amino acid, 0.1 to 1.0% (w/v) of mannitol, a water-soluble inorganic salt, and a buffering reagent.

As discussed above, support for amended claim 1 is found in the instant application as well as in the priority document Korean application KR 10-2003-0037060. Specifically, support for each of the elements in amended claim 1 is detailed below.

With regard to the instant application, support can be found for the nonionic surfactant on page 6, lines 21-22. Support can be found for 0.0001 to 0.1% (w/v) of polyhydric alcohol on page 8, lines 10-11 and page 9, lines 4-5. Support for the neutral amino acid can be found on page 7, lines 20-22. Support for 0.1 to 1.0% (w/v) mannitol can be found on page 9, lines 11-14. Support for the water-soluble inorganic salt can be found on page 10, lines 1-7. Support for the buffering reagent can be found on page 10, lines 20-21.

With regard to the Korean priority application 10-2003-0037060, and with reference to the original English translation, support can be found for the nonionic surfactant on page 7, lines 19-20; support for 0.0001 to 0.1% (w/v) of polyhydric alcohol can be found on page 9, lines 9-10 and 18; support for the neutral amino acid can be found on page 8, lines 22-24; and support for the water-soluble inorganic salt can be found on page 9, line 21 to page 10, line 1. With reference to the new English translation(s) provided herewith, support for 0.1 to 1.0% (w/v) mannitol can be found in the last two lines of the translated paragraph.

Thus, as detailed above, support for the presently claimed invention is described in both the instant application and in the Korean priority application. Furthermore, since the claimed invention is described in the Korean priority application, Applicant's claim for priority to the date of June 10, 2003, the filing date of the Korean priority application, is thus perfected.

As mentioned above, Vukmirovic is prior art only under 35 U.S.C. § 102(e). With regard to Vukmirovic, the effective priority date of WO 2004/006958 to Vukmirovic is the PCT filing date of July 14, 2003. Thus, Vukmirovic was filed after the effective priority date of the instant application and therefore is not a proper §102(e) reference.

Applicants therefore request withdrawal of this rejection and an allowance of the claims.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance are requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

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